JAN 2 4 2006

K053606

510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

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Contact Person: Carri Graham

Date: December 22, 2005

807.92(a)(2)

Trade Name: BE Plus / AURA-LTM64 Amplifier

Common Name: Physiological Signal Amplifier

Classification Name(s): Physiological Signal Amplifier

Classification Number: 84GWL

807.92(a)(3)

Predicate Device(s)

EB Neuro, S.p.A.	MIZAR Amplifier	K003154
EB Neuro, S.p.A.	NIC36 Amplifier	K041198

Additional Substantial Equivalence Information is provided in the following Substantial Equivalence Comparison Table.

807.92 (a)(4)

Device Description

The BE Plus / AURA-LTM64 Amplifier is a fully programmable system which provides a total of 64 analog input channels each of which can be configured, amplified and converted to digital form (analog to digital conversion). The amplifier receives its power from a dedicated AC/DC adapter, meeting the IEC 60601-1 requirements, which feeds a +15VDC. Internally, the +15VDC is further isolated by a dedicated DC/DC CF type converter.

The BE Plus / AURA-LTM64 Amplifier is intended to be used to amplify and filter bioelectric signals captured via a lead or transducer on the surface of the human body. It captures the data, converts it into a digital form and passes it on to a host computer running appropriate amplification software. Typical fields of application will be: Electroencephalograph (EEG), Evoked Potentials (EP), Polysomnography (Sleep Analysis) and General Polygraphy.

The BE Plus / AURA-LTM64 Amplifier does not contains a Pulse Oximeter module.

The host computer must use one of the following Operating Systems: Microsoft Windows 98, Microsoft Windows NT or Microsoft Windows XP.

The BE Plus / AURA-LTM64 Amplifier system consists of three interconnected units: the amplifier box, the PC interface (PCMCIA interface or BE Net) and the AC/DC adapter; optionally the system may be completed by a led visual stimulator.

807.92(a)(5)

Intended Use(s)

The BE Plus / AURA-LTM64 Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

807.92(a)(6)

Technological Characteristics

Item	EB Neuro MIZAR Amplifier K003154	EB Neuro Nic36 Amplifier K041198	EB Neuro BE Plus / AURA-LTM64 Amplifier This Submission
Intended use	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these to a PC during recording of neurophysiology examinations	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these to a PC during recording of neurophysiology examinations	Acquisition of EEG, polygraphy and polysomnography signals and transmission of these to a PC during recording of neurophysiology examinations
EEG/Polygraphic channel	32/40 (64/96/128 with expansion boards)	36 monopolar fixed – (no expansion boards)	64 monopolar (128 with the double Amplifier configuration expansion)
DC channel	32/40	4	4
A/D conversion	16 bit Sigma-Delta A/D effectively transferred to host	16 bit SAR effectively transferred to host	16 bit SAR effectively transferred to host
Sampling rate	User selectable (128, 256, 512 . . . up to 32KHz/Channel)	User selectable (128, 256, 512 . . . up to 8192 Hz/Channel)	User selectable (128, 256, 512 . . . up to 4096 Hz/Channel)
CMRR	>100dB	>100dB	>100dB
Noise	<1.5μVpp (0.5μVrms)	<0.5μVrms (AC) <7μVrms (DC)	<0.5μVrms (AC) <7μVrms (DC)
Power Supply	External IEC 60601-1 Mains Internal batteries (optional)	External IEC 60601-1 Mains	External IEC 60601-1 Mains
Internal storage	N/A	N/A	Auxiliary FLASH memory to accumulate data when optical link is temporary unconnected.
Time marker of data acquisition flow	N/A	N/A	Real time clock on board. Precision of hundreds of seconds. Coin battery auxiliary supply.
Amplifier – PC Interface	PCMCIA or BE Net	PCMCIA (NicPCMCIA) or BE Net (NicNet)	PCMCIA or BE Net

Item	EB Neuro MIZAR Amplifier K003154	EB Neuro Nic36 Amplifier K041198	EB Neuro BE Plus / AURA-LTM64 Amplifier This Submission
Other Interfaces	128x64 graph LCD display 5 push buttons	Power On LED / LED matrix Ohm Meter	Power On LED (bicolor) / LED matrix Ohm Meter
Use standard sensors and electrodes	Yes (electrodes and sensors are not included with the Amplifier)	Yes (electrodes and sensors are not included with the Amplifier)	Yes (electrodes and sensors are not included with the Amplifier)
Dimension	250 (L) x 170 (W) x 65 (H) (mm)	203 (L) x 135 (W) x 38 (H) (mm)	194 (L) x 125 (W) x 37 (H) (mm)
Case material	Polycarbonate plastic	Polycarbonate plastic	Polycarbonate plastic
Total weight	1.5 Kg	0.55 Kg	0.48 Kg
Isolation	Fiber optic link Patient isolation BF type Auxiliary I/O components ports: N°2 BF type N°1 B type	Fiber optic link Patient isolation CF type Auxiliary I/O components ports: N°2 B type	Fiber optic link Patient isolation CF type Auxiliary I/O components ports: N°2 B type
Safety Standard	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 60601-1-4	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 60601-2-40 IEC 60601-1-4	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-26 IEC 60601-2-40 IEC 60601-1-4
System Components	Amplifier Head box AC/DC Adapter PCMCIA or BE Net Interfaces DC Input box (optional) LED Flash stimulator (optional)	Amplifier AC/DC Adapter PCMCIA (NicPCMCIA) or BE Net (NicNet) Interfaces DC Input box (NicDCIN) (optional) LED Flash stimulator (NicLED Photic Stimulator) (optional)	Amplifier AC/DC Adapter PCMCIA or BE Net Interfaces DC Input box (optional) LED Flash stimulator (optional)
Firmware	Resident and Runtime downloadable	Resident and Runtime downloadable	Resident and Runtime downloadable
Patient connection and inputs	32 Monopolar inputs – 32 plugs 8 Bipolar inputs – 16 plugs 1 Thermistor – 2 plugs 2 Reference inputs – 2 plugs 14 ISO GROUND inputs – 14 plugs	36 Monopolar inputs – 36 plugs 2 Reference inputs – 2 plugs 2 ISO GROUND inputs – 2 plugs	64 Monopolar inputs – 64 plugs 2 References inputs – 2 plugs 2 ISO GROUND inputs – 2 plugs

Item	EB Neuro MIZAR Amplifier K003154	EB Neuro Nic36 Amplifier K041198	EB Neuro BE Plus / AURA-LTM64 Amplifier This Submission
I/O connections	1 Fiber optic port 1 AC/DC Adapter port 3 Auxiliary components port: generic TX/RX serial I/O, LED Flash stimulator, pression button connector	1 Fiber optic port 2 Auxiliary components port: AC/DC Adapter, generic TX/RX serial I/O, DC Input box (NicDCIN), LED Flash stimulator (NicLED Photic Stimulator)	1 Fiber optic port 1 Auxiliary components port: AC/DC Adapter, generic TX/RX serial I/O, DC Input box, LED Flash stimulator 1 Amplifier Link expansion port: AC/DC Adapter, BE Plus/AURA-LTM64 Amplifier

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 24 2006

EB Neuro, S.P.A.
c/o Ms. Carri Graham
Anson Group
11460 N. Meridian Street, Suite 150
Carmel, Indiana 46032

Re: K053606
Trade/Device Name: BE Plus / AURA-LTM64 Amplifier
Regulation Number: 21 CFR 882.1835
Regulation Name: Physiological signal amplifier
Regulatory Class: II
Product Code: GWL
Dated: December 21, 2005
Received: December 27, 2005

Dear Ms. Graham:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Richmond for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: BE Plus / AURA-LTM64 Amplifier

Indications For Use:

The BE Plus / AURA-LTM64 Amplifier is intended to be used by or under the direction of a physician for acquisition of EEG, polygraphy and polysomnography signals and transmission of these signals to a PC during recording of neurophysiology examinations.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruchup for MKM

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053606